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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559

26646 7590 06/08/2009

KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/887,204	FLESHNER-BARAK ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-96 and 113-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-96 and 113-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt request for extension of time, declaration under 37 CFR 1.132, amendment and remarks filed 3/16/09. Claim 118 is amended. Claims 90-96 and 113-131 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 90-96 and 113-131 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525) according to the rejections on record and reiterated herein.

Burnside discloses multiple pulsed dose drug delivery system (abstract) comprising a core (column 6, lines 52-56) that includes one or more amphetamine salts coated with immediate release coating and one or more amphetamine salts that are covered with enteric coating (column 3, lines 25-48; column 4), and additives, the additives are binders, disintegration agent, filling agent, surfactant, solubilizers and stabilizers (column 6, line 64; column 7, lines 1, 6, 11, 14 and 18). Hydroxypropyl methylcellulose is an example of a binder additive (column 6, lines 63-67); cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) are examples of disintegration agents (column 7, lines 1-5); mannitol, lactose, polyethylene glycol are few of the fillers in Burnside (column 7, lines 6-10); PLURONIC is a surfactant in Burnside (column 7, lines 10-13); methylphenidate is specifically disclosed as an amphetamine derivative (column 7, lines 48-55).

The cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) meet the limitation of the claimed disintegration agents. Claims 113 and 114 recite the properties of the composition and the recited properties are inherent to the composition.

Claim 115 recites the characteristic of the particles and is met by the art.

Claims 116 and 117 administer the composition of claims 90 and 93 to a person in need thereof to treat hyperactivity and since Burnside administers the dosage form and acknowledges that that methylphenidate can treat attention deficit hyperactivity (column 7, lines 51-55), the administered dosage would inherently treat hyperactivity and claims 116 and 117 are met.

The prior art teaches the presence hydroxypropyl methylcellulose, cross-linked carboxymethylcellulose and sodium starch glycolate so that claims 122-125 are met.

The particles of Burnside are coated with hydrophilic or hydrophobic polymers namely hydroxypropyl methylcellulose polyvinylpyrrolidone, ethylcellulose, EUDRAGIT polymers and other enteric polymers (column 7, line 42 to column 8, line 45) meeting new claims 118-121.

Burnside discloses a composition comprising disintegration agent and methylphenidate and the composition is multi-particulate with some cores coated with enteric coating material and others coated with immediate release coating materials. The formulation of Burnside does not contain tannic acid or tannin or gallotannin or gallotannic acid.

However, Methylphenidate has been known to be formulated with tannic acid for controlled solubility of the methylphenidate according to Swanson (column 4, lines 45-49; column 7, line 16, 44; column 8, line 16). The claims recite ranges in amounts of superdisintegrants, hydrogel and tannic acid. However, there is no demonstration that the recited amounts provide unexpected results to the claimed dosage form. Specifically, Burnside is silent in the amounts of these ingredients, which implies that any amount in any combination would provide formulation for the effective release of methylphenidate. Claims 126-131 are compositions comprising various amounts of tannic acid, hydroxypropylmethylcellulose and hydroxypropylcellulose and superdisintegrants and in that wise are similar to claim 90 except for the specific hydrogel materials of hydroxypropylmethylcellulose and hydroxypropylcellulose claims. Furthermore, the claimed broad ranges suggest varied combinations in varied amounts. In the absence of factual evidence, the recited amounts of the hydrogel composition, the tannic acid and the superdisintegrants would not distinguish the claimed invention over the prior art.

Therefore, taking the combined teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that

inclusion of tannin or tannic acid into the composition of Burnside would provide controlled solubility of methylphenidate.

Response to Arguments

4. Applicant's arguments filed 3/16/09 have been fully considered but they are not persuasive.

5. Applicant says that on September 24, 2008, applicant had submitted that the examiner had not established a prima facie case of obviousness based on Burnside and Swanson. The examiner also notes that a response to the arguments of September 24, 2008 was given in the office action of 11/17/08 at paragraph 5, beginning at page 5 and ending at page 8.

6. a) Applicant says that 1.132 declaration by Vered Rosenberger shows that "gel formulation should contain superdisintegrant, tannic acid, and hydrogel in relative amounts within the respectively recited ranges to have good expansion and strength suitable for use as gastric retention vehicle," and that Table 1 of the 132 declaration shows that an overall expansion and strength was obtained with about 4% to 8% tannic acid and about 30% $\pm$ 2% croscarmellose sodium disintegrant; that Table 2 of the 132 declaration shows that formulations having no tannic acid exhibited no expansion; and that declarant's experience is that the amount of tannic acid can be decreased to about 2% provided that the amount of the superdisintegrant is increased to greater than about 32% and the relative amounts of Klucel and Methocel are adjusted.

7. With respect to applicant's arguments in a), the examiner will address the 132 declaration under a separate heading. However, claim 90 recites a range of about 2% to about 12% for the

tannic acid, about 10% to about 75% superdisintegrant and about 20 to about 70% of hydrogel while the data in the declaration uses specific superdisintegrants and specific hydrogel polymers so that the data in the Tables represents specific composition that is different from claim 90. Also the tannic acid range of 4-8% is within the recited range but there are no points outside of the ranges to show the effect. Thus, the data is not commensurate with the claims because applicant has not showed that other superdisintegrant will or will not produce the expected expansion when combined with tannic acid.

8. b) Applicant argues that the combination of Burnside with Swanson would not have rendered the claimed composition obvious because the skilled artisan would not have expected that relative amounts of superdisintegrant, tannic acid and hydrogel would affect the expansion and strength of gel formulation and because the experimental data demonstrates gel formation must contain relative amounts of superdisintegrant, tannic acid and hydrogel. The examiner disagrees. The composition in claims 90 and 93 are not gels. Swanson and Burnside teach methylphenidate compositions so that the combined composition of Swanson and Burnside would have the same utility and the artisan has the skills of using appropriate amounts of superdisintegrant, tannic acid and hydrogel to produce composition where the methylphenidate exhibits controlled solubility in the presence of the tannic acid. The properties of tannic acid and superdisintegrants would be the same in the claimed composition and the disclosed composition since compounds and/or products cannot be separated from their properties. Because the specific compositions in the data are not commensurate with the claimed compositions as it regards the % range of the tannic acid in the claims v. the data and the specific superdisintegrants in the data v. the generic disintegrants in the claims, it is noted that the data

does not provide unexpected results over the combined composition derived from the teachings of Burnside in view of Swanson when compared with what is claimed.

9. Claims 90, 93, 116 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525) and further in view of Baker et al. (US 5,874,090).

Burnside in view of Swanson has been shown above to render obvious claims 90 and 93 obvious. While Burnside recognizes that methylphenidate is indicated in the treatment of attention deficit hyperactivity disorder (column 7, lines 51-55), Burnside does not specifically describe treating attention deficit disorder. However, Baker teaches that methylphenidate can be administered to a subject in need thereof to treat hyperactivity (claims 1-10 and 16). Therefore, taking the teachings of Burnside, Swanson and Baker together, the person of ordinary skill in the art at the time the invention was made would have reasonable expectation of success that administering the composition of Burnside containing the tannic acid of Swanson to person in need thereof, would treat hyperactivity as suggested by Baker.

Response to Arguments

10. Applicant's arguments filed 3/16/09 have been fully considered but they are not persuasive.

11. Applicant argues claims 90 and 93 are not obvious over Burnside in view of Swanson, that Baker does not teach inclusion of hydrogel, superdisintegrant and tannic acid in its formulation, Baker does not provide what is missing in Burnside and Swanson and that since the base claims 90 and 93 are not obvious over Burnside, Swanson and Baker, method claims 90 and 93 that depend on the base claims 90 and 93 are not also obvious.

12. The examiner disagrees. Burnside teaches composition comprising methylphenidate and hydrogel polymer. Swanson was relied upon for teaching that tannic acid controls the solubility of methylphenidate. The artisan has the capability of formulating compositions containing methylphenidate, tannic acid and hydrogel polymers in amounts that would produce composition in which the solubility of the methylphenidate is controlled. Methylphenidate is known to treat attention deficit hyperactivity and since Burnside administers the composition, the dosage form would inherently treat hyperactivity. However, Baker positively teaches that methylphenidate is administered to treat hyperactivity. Thus, Baker is not relied upon to provide a teaching of including hydrogel, superdisintegrant and tannic in a composition. Therefore, the base claims having been shown to be obvious over Burnside in view of Swanson, the method claims 116 and 117 are also obvious over Burnside in view of Swanson and further in view of Baker.

13. Declaration under 37 CFR 1.132 by Vered Rosenberger, Ph.D.

14. The declaration under 37 CFR 1.132 filed 3/16/09 is insufficient to overcome the rejection of claims 90-96 and 113-131 based upon Burnside in view of Swanson and Burnside in view of Swanson and further in view of Baker as set forth in the last Office action because: the data in the declaration is not commensurate with the claims. For example, claims 90 and 93 used generic hydrogel and the composition in the declaration uses specific hydrogel, Klucel and Methocel; claims 90 and 93 use generic superdisintegrants and the composition in the declaration uses specific disintegrant, croscarmellose; the declarant says that optimum expansion and strength is achieved with about 4% to about 8% tannic acid and 28% to 32% superdisintegrant, which in the declaration is specific to croscarmellose, while claims 90 and 93 recite a range of about 2 to about 12% tannic acid and about 10 to about 75% of broad/generic superdisintegrant.

Even if the tannic acid amount is increased to 12%, it does not address the recited range of about 2 to about 12%; and even if the % of the specific superdisintegrant is greater than about 32%, it does not address the range of about 10 to about 75% for the generic superdisintegrant.

No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618